

Applicant: Garrity et al.
Serial No.: 09/761,969
Filed: January 16, 2001
Page 2 of 12

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A kit for determining a concentration of ~~a vitamin D component~~ 25-hydroxy vitamin D (25-OH-D) in a sample, comprising:

a releasing composition including from about 0.01 to about 5% of a cyclodextrin, from about 0.01 to about 5% of a sodium salicylate, and from about 0.1 to about 1.0M NaOH, the cyclodextrin, the salicylate, and the NaOH being provided in an amount effective to reduce interference from a protein or a lipid with ~~a vitamin D component~~ 25-hydroxy vitamin D present in a sample; and

25-hydroxy vitamin D coupled to a solid phase;

vitamin D binding protein; and

a vitamin D binding protein antibody coupled to a label present in an amount that produces a detectable signal when 25-hydroxy vitamin D is present in the sample

~~a detecting composition including a label provided in an amount to produce a detectable signal when the vitamin D component is present in the sample.~~

2. (Currently amended) A kit of claim 1, wherein the cyclodextrin, the salicylate, and the ~~aqueous base component~~ NaOH are provided in an amount effective to reduce interference from proteins or fatty acids with ~~a vitamin D component~~ 25-hydroxy vitamin D present in a sample of a mammal fluid.

3. (Previously presented) A kit of claim 2 wherein the mammal fluid is selected from the group consisting of milk, whole blood, serum, and plasma.

4. (Previously presented) A kit of claim 2 wherein the mammal fluid comprises a human serum.

Applicant: Garrity et al.
Serial No.: 09/761,969
Filed: January 16, 2001
Page 3 of 12

5-10. (Cancelled)

11. (Previously presented) A kit of claim 1 wherein the releasing composition comprises about 0.35 to about 0.5 M of NaOH.

12. (Previously presented) A kit of claim 1 wherein the releasing composition is free of an organic solvent.

13-14. (Cancelled)

15. (Previously presented) A kit of claim 1 wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin and a beta-methylated cyclodextrin.

16. (Cancelled)

17. (Previously presented) A kit of claim 1 wherein the releasing composition comprises about 2% of an alpha-cyclodextrin.

18. (Previously presented) A kit of claim 1 wherein the releasing composition comprises about 0.05% of a beta-methylated cyclodextrin.

19. (Previously presented) A kit of claim 1 wherein the releasing composition comprises about 0.5 to about 5% of the sodium salicylate.

20. (Previously presented) A kit of claim 1 wherein the releasing composition further comprises about 0.01 to about 0.1% of a surfactant.

21. (Cancelled)

Applicant: Garrity et al.
Serial No.: 09/761,969
Filed: January 16, 2001
Page 4 of 12

22. (Original) A kit of claim 1 wherein the releasing composition forms a homogeneous mixture with a mammal fluid.

23-26. (Cancelled)

27. (Currently amended) A kit of claim ~~[[25]]~~ 1 wherein ~~the host component is labeled with the label is selected from the group consisting of~~ a chemiluminescent label, a fluorescent label ~~[[or]] and~~ a radio-active label.

28. (Currently amended) A kit of claim ~~[[25]]~~ 1 wherein ~~the host component is an antibody labeled with acridinium~~ vitamin D binding protein antibody is an acridinium-labeled antibody.

29. (Cancelled)

30. (Currently amended) A kit of claim ~~[[29]]~~ 1 wherein ~~the separator component comprises a magnetic particle~~ solid phase is a magnetic particle.

31-37. (Cancelled)

38. (Currently amended) A kit of claim ~~[[25]]~~ 1 wherein the 25-hydroxy vitamin D coupled to a solid phase is in the form of 25-hydroxy vitamin D coated magnetic particles, the vitamin D binding protein antibody is coupled to an acridinium label, and the 25-hydroxy vitamin D coated magnetic particles, the acridinium labeled vitamin D binding protein antibody, and the vitamin D binding protein are present in a single composition ~~partner component competes with a vitamin D component to form a complex with the host component, the partner component comprises a vitamin D component linked to a magnetic particle, the partner component binds to the host component through a vitamin D binding protein, the host component comprises an antibody labeled with acridinium.~~

39-84. (Cancelled)

Applicant: Garrity et al.
Serial No.: 09/761,969
Filed: January 16, 2001
Page 5 of 12

85. (Currently amended) A kit of claim 1, wherein the releasing composition further includes from about 0.01% to about 0.1% of a surfactant, and ~~wherein the detecting composition includes an~~ the antibody is labeled with acridinium.

86. (Withdrawn) A kit for determining an amount of 25-hydroxy Vitamin D (25-OH-D) in a sample, comprising:

a composition including a cyclodextrin, a salicylate, and an aqueous base component selected from the group consisting of NaOH and KOH, the cyclodextrin, the salicylate, and the aqueous base component being provided in an amount effective to reduce interference from a protein or a lipid with 25-OH-D present in the sample;

and a plurality of reagents including 25-OH-D coupled to a solid phase, and a label provided in an amount to produce a detectable signal when 25-OH-D is present in the sample.

87. (Withdrawn) The kit of claim 86, wherein the plurality of reagents further comprise at least one of a vitamin D-binding protein (DBP), and a labeled antibody that binds DBP.

88. (Currently amended) The kit of claim ~~[[86]]~~ 87, wherein the antibody is labeled with a chemiluminescent label.

89. (Withdrawn) The kit of claim 88, wherein the antibody is an acridinium labeled anti-DBP antibody.

90. (Withdrawn) The kit of claim 86, wherein the composition comprises about 0.1 M to about 1.0 M NaOH or KOH, about 0% to about 5% cyclodextrin, and about 0% to about 1% salicylate.

91. (Withdrawn) The kit of claim 86, wherein the solid phase comprises magnetic particles.

Applicant: Garrity et al.
Serial No.: 09/761,969
Filed: January 16, 2001
Page 6 of 12

92. (Withdrawn) The kit of claim 86; wherein the plurality of reagents are provided in a composition having a pH between about 6 to about 9.

93. (Withdrawn) The kit of claim 86, wherein the composition further comprises a surfactant.